EnSiteTM HD Grid Catheter Mapping System for Advanced High Density (HD) Three-Dimensional Mapping in Non-Paroxysmal Atrial Fibrillation and Atrial Tachycardi

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To demonstrate the safety, feasibility and performance of the EnSite HD Grid Catheter mapping system for advanced high-density three-dimensional mapping in patients undergoing catheter ablation procedures for the treatment of non-paroxysmal atrial...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON45653

Source
ToetsingOnline

Brief title
EnSite HD Grid Catheter AF/AT Mapping Study

Condition

- Cardiac arrhythmias

Synonym
Atrial fibrillation, heart rhythm disorder

Research involving
Human

Sponsors and support

Primary sponsor: St. Jude Medical
Source(s) of monetary or material Support: St Jude Medical

Intervention

Keyword: Atrial tachycardie, Ensite Precision, HD Grid mapping, Non paroxysmaal AF

Outcome measures

Primary outcome

Safety Endpoint: the proportion of subjects who experience intra-procedure and/or post-procedure serious adverse events within 48 hours from the mapping procedure.

Feasibility Endpoints:

* Determination of atrial areas with fast and regular activities in the left atrium will be summarized by the proportion of subjects with each of the following arrhythmia location: coronary sinus, LA appendage, posterior wall, roof, mitral isthmus, left superior pulmonary vein, right superior pulmonary vein, left inferior pulmonary vein, right inferior pulmonary vein, septum, and any other location that was mapped.

Performance Endpoints:

* Geometry creation will be assessed by:

o The HD Grid Catheter*s ability to be maneuvered to all desired anatomic locations,

o The incidence of induced ectopic beats or other arrhythmias occurring during

HD Grid Catheter maneuvering,

o The HD Grid Catheters ability to contact cardiac tissue,

o Determination if field scaling is appropriate when using the HD Grid Catheter

o Geometry created with the HD Grid Catheter is comparable to the subjects CT/MRI (if CT/MRI is available)

Secondary outcome

Feasibility endpoints:

* Determination of atrial areas with fast and regular activities in the right atrium will be summarized by the proportion of subjects with each of the following arrhythmia locations: anterior wall, appendage, posterior wall, roof, septum, other. Additionally, the average (+/- standard deviation) of the cycle length for each location will be summarized.

* Complex fractionated electrograms will be summarized as the proportion of subjects in whom a complex fractionated electrogram (defined as electrograms that have low peak-to-peak amplitude and a cycle length of * 120 ms) was identified.

* Consistent direction of wave front propagation will be summarized by the average and standard deviation of the number of map points, the conduction velocity and activation duration.

Performance endpoints:

* Map repeatability will be characterized by evaluating substrate conduction velocity maps created using the HD Grid Catheter mapping system pre-ablation compared to repeat pre-ablation.

* Demonstrate that the post-ablation map created with the HD Grid Catheter shows a change corresponding to the ablation result (i.e. sinus rhythm)

* The HD Grid Catheter electrogram signals will be assessed by:

o The proportion of electrograms collected with the HD Grid Catheter that have better quality/less noise than electrograms collected with the ablation catheter at the same selected cardiac location

o The proportion of electrogram wave form traces from the HD Grid Catheter that could be used to help diagnose the subject

Other secundairy endpoints

* Total mapping time * retrospective analysis

* Number of map points collected * retrospective analysis

* Number of RF ablations * from the Ampere generator * retrospective analysis

* Total RF application time * from the Ampere generator * retrospective analysis

* Occurrence of repeat ablations (incidence and time from index procedure)

* Incidence of all SAEs up to and including the 6 month follow-up visit as adjudicated by the Clinical Events Committee (CEC)

* Percentage of subjects free of symptomatic and/or asymptomatic episodes of study arrhythmia lasting longer than 30 seconds at 6 month follow-up visit (use of a previously ineffective drug does not constitute treatment failure)

* Percentage of subjects free from any arrhythmia lasting longer than 30 seconds at 6 month follow-up visit (use of a previously ineffective drug does not constitute treatment failure)

* EQ5D Quality of Life Assessment (Enrollment/Baseline, 30 days, 3, and 6

months)

* AFEQT Quality of Life Assessment for AF subjects (Enrollment/Baseline, 30

days, 3, and 6 months)

Study description

Background summary

Catheter ablation is an established treatment option for patients with atrial fibrillation (AF) and left atrial tachycardia (AT). Catheter ablation for non-paroxysmal AF is more complex as triggers, if present at all, are not immediately apparent, but the abnormal atrial substrates are the likely predominant mechanisms.10-12 Additional catheter ablation strategies targeting for atrial substrate modification have been introduced. The common strategies involve either application of empirical linear lesion sets in the atrial areas or ablation of atrial areas with complex fractionated atrial electrograms in addition to pulmonary vein isolation. Nevertheless, the corresponding success rates in long-term sinus rhythm maintenance are modest.
Non-paroxysmal AF and left AT are characterized by fast and regular atrial activities, complex fractionated atrial electrograms, consistent direction of wave front propagation, and low peak-to-peak voltage.2-3, 5, 13-21 Advanced high-density three-dimensional catheter mapping strategies to target the evaluation of these characteristics and mechanisms responsible for the AF and left AT, identification of atrial areas with low peak-to-peak voltages and determination of the *critical* atrial targets for catheter ablation during the procedures would be essential.
In this clinical evaluation a new high density 3 dimensional catheter mapping system will be tested in subjects who are indicated to get a catheter ablation procedure for non-paroxysmal AF.

Study objective

To demonstrate the safety, feasibility and performance of the EnSite HD Grid Catheter mapping system for advanced high-density three-dimensional mapping in patients undergoing catheter ablation procedures for the treatment of non-paroxysmal atrial fibrillation (AF) or left atrial tachycardia (AT)

Study design

This is a prospective, single-arm, multi-center clinical investigation.

Intervention

Catheter ablation

Study burden and risks

There is minimal to no additional risk associated with participation. The participants do have to come back to the outclinic for two additional follow up visits at 30 days and 3 months in addition to the normal 6 months follow up visit. And they will have to fill out 2 QoL questionnaires at each follow up visit.
The use of HD Grid mapping prior to the ablation procedure might possibly lead to a better treatment result.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Presence of non-paroxysmal atrial fibrillation (AF) or left atrial tachycardia (AT) referred for catheter ablation
2. Age of 18 years of age or older at time of Enrollment
3. On continuous anticoagulation (INR 2-3) for >4 weeks prior to the ablation
4. Able and willing to provide written informed consent to participate in this clinical investigation

Exclusion criteria

1. Secondary atrial fibrillation (AF)
2. Presence of a prosthetic valve(s) or hemodynamically significant valvular heart disease as determined by Study Investigator
3. Active systemic infection (e.g. sepsis)
4. Presence of left atrial thrombus (i.e., positive TEE) or myxoma, or interatrial baffle or patch via the transseptal approach
5. Contraindication to systemic anticoagulation (i.e., heparin, warfarin, or a direct thrombin inhibitor)
6. History of cerebrovascular accidents (Stroke, TIA)
7. Previous myocardial infarction, unstable angina pectoris or coronary artery by-pass <180 days at Enrollment or cardiovascular intervention expected in the 180 days post-Enrollment
8. Left atrial size >55mm
9. NYHA functional class III or IV heart failure
10. Left ventricular ejection fraction <35%
11. Uncontrolled Hyperthyroidism
12. Pregnant or of childbearing potential and not using adequate contraceptive methods or nursing
13. Participating in another clinical investigation that may confound the results of this clinical investigation
14. Life expectancy less than 12 months, as determined by Study Investigator
15. Severe clinical condition (e.g. active carcinoma) that, in the opinion of the Study Investigator, excludes the participation in the study

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	HD Grid Mapping Catheter
Registration:	No

Ethics review

Approved WMO

Date:	26-06-2017
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL59389.058.16